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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,666	02/15/2002	Tsuneji Suzuki	054160-5060	7720

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EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,666	SUZUKI ET AL.	
	Examiner	Art Unit	
	Gollamudi S Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8-25-04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *32-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The RCE filed on 8-25-04 is acknowledged.

Claims included in the prosecution are 32-38.

Claim Rejections - JJ USC # 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this office action'.

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in

section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 32-33 and 35-38 are rejected under 35 U.S.C. l03 (a) as being unpatentable over EP 0847 992 (Suzuki et al).

EP teaches benzamide derivative claimed by applicant (see claim 14). Additionally, EP teaches that the active ingredient may be used in general pharmaceutical compositions, and may be prepared with generally used diluents or excipients, such as binders, extenders, fillers, moisturizers, disintegrants, surfactants, and lubricants. EP also teaches that the pharmaceutical dosage form can be a tablet, pill, powder, solution, suspension, emulsion, granules, capsule, injection or suppository.

More specifically, EP teaches the use of calcium carbonate, amino acids, starch, methyl celluloses, calcium carmellose, lactose, sugars, stearates, talc, polyethylene glycol, sodium alginate and many other well known excipients (page 46, lines 5- 39). The use of these excipients in combination with claimed benzamide derivative would have been obvious to one of ordinary skill in the art with a reasonable expectation of success, since EP is suggestive of these art known excipients together with the benzamide derivative.

3. Claims 32-34 and 38 are rejected under 35 U.S.C. l03 (a) as being unpatentable over EP 0847 992 in view of the International Cosmetic Ingredient Dictionary and Handbook.

EP described above as teaching pharmaceutical compositions comprising benzamide derivatives. EP teaches the inclusion of many well-known pharmaceutical excipients. EP does not teach the inclusion of each of the specific excipients claimed by Applicant. EP does not specifically teach hydroxypropyl cellulose or mannitol or claimed amino compound or organic and inorganic salts. The International Cosmetic Ingredient Dictionary and Handbook is relied upon for the teachings that mannitol and hydroxypropyl cellulose as well known binders, as well as the teaching that hydroxypropyl methylcellulose is a well-known film former. Lastly, the Dictionary and Handbook is relied upon for the teaching that inorganic compounds such as sodium bicarbonate, disodium phosphate, potassium bicarbonate and ammonia, as well as amino compounds such as triethanolamine, diethanolamine, diisopropanolamine, and triisopropanolamine, as well as organic acid salts such as sodium fumarate, and

trisodium phosphate are all well known pH adjusters. Each of these types of excipients (binders, film formers and pH adjusters) are well known excipients used in the making of pharmaceutical formulations. Therefore, their inclusion in a pharmaceutical composition, which allows for necessary excipients, is not found to be patentable. The selection of a known material based on its suitability for its intended use is obvious, absent a clear showing of unexpected results attributable to the Applicant's specific selection. One skilled in the art would have been motivated to include the well-known excipients discussed above in the compositions described by EP with a reasonable expectation of success. The motivation to do so lies in the teaching of EP that well known excipients can be included in their formulation. Adjusting the pH of a composition is deemed to be within the skill of the art since that is routinely practiced in the fields of Chemistry and Biochemistry. The criticality of the product produced by dry granulation is unclear since one of ordinary skill in the art would avoid wet granulation process if the moisture leads to the degradation of the active agent. Therefore, this invention as a whole would have been prima-facie obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant pointing to Table 1 results and argues what while some compounds such as corn starch were found to accelerate the rate or decomposition of the benzamide derivative of formula (3), (compound 1), others such as gelatinized starch, magnesium stearate and others stabilize the compound 1. These arguments are not found to be persuasive since a careful examination of the results in the Table

indicate not much of a difference between the control value (0.18) and others claimed to be providing stability (see for example mannitol (0.21), hydroxypropyl cellulose (0.20), Magnesium stearate (0.22). From these values it is unclear to the examiner as to one can argue about unexpected results. Furthermore, formula 1 encompasses three different compounds and it is unclear whether the claimed excipients behave the same way with all three compounds. Prior art teaches the same benzamide compound and is suggestive of various excipients in combination with this compound. Instant invention containing art known additives therefore, is prima facie obvious to one of ordinary skill in the art.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 32-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,638,530. Although the conflicting claims are not identical, they are not patentably distinct from each other because: Instant claims are drawn to a combination of the

benzamide derivative of formula I in combination with an amino compound (such as glycine) and a solvent which is polyethylene glycol. According to instant claim 38, the preparation is pH adjusted, meaning that there is a mineral acid (see example 5 of instant specification). The patented claims are drawn to a combination of the same benzamide derivatives in combination with amino compounds such as glycine hydrochloride and a mineral acid. Patented claims are therefore, within the scope of instant generic claims.

5. Claims 32-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-32 of U.S. Patent No. 6,174905. Although the conflicting claims are not identical, they are not patentably distinct from each other because: Instant claims are drawn to a combination of the benzamide derivative of formula I which encompasses three specific compounds in combination with any of the several compounds (excipients). The patented claims recite benzamide derivatives encompassing several compounds including instant compounds in combination with the same excipients. Instant claims are therefore, within the scope of the patented claims.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

G S Kishore

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK